NATIONAL INSTITUTES OF HEALTH
Meeting of the NIH Deputy Ethics Counselors and Ethics Coordinators

Minutes – November 9, 2004
1:00 to 3:00 pm

1. Representational Issues Gretchen Weaver

Employees have apparently asked whether they need to have an outside activity approved to serve on the Boards of entities/companies doing business with the NIH for the benefit of employees, such as the companies that run the childcare facilities, the R & W, and the credit union. The answer is that unless the activity is appropriate as an official duty activity (such as the NIH Chidlcare Board, or the R & W advisory council which invites ICs to serve (not the individuals, as individuals)), they need to seek outside activity approval under the HHS Supplemental Regulations.

It is important to advise employees undertaking these activities as outside activities, that 18 USC 203 and 205 prohibit employees from representing the interests of third parties to/before any Federal agency. If the activity is a compensated outside activity, the employee needs to be especially careful about this. If the activity is uncompensated, an exception in 205, as interpreted by the Department of Justice, may permit certain representational activities. But, employees should be advised that they should not make any representation to an agency until they have consulted with their ethics official to ensure that under the facts presented, the exception applies. The Department of Justice discourages individual representational activities, even where the exception applies, and encourages agencies to require that these entities identify a non-federal employee to have all representational contacts with the agency.

2. Long Term Training Needs for Ethics Staff Traci Melvin

Ethics staff were asked about their long-term training needs to enhance their own knowledge and ability to function efficiently and effectively as ethics specialists and Deputy Ethics Counselors. In the past, the NIH Ethics Office has offered a Basic Introduction to Ethics for Ethics Staff (“Ethics 101") targeted at staff who will work in an IC Ethics Office. The course was well-received, and students have asked for additional sessions and a higher level course. This course teaches students what it means to be an ethics specialist and their role in an ethics office, and is totally separate from the annual HHS DEC Workshop sponsored by the HHS Office of the General Counsel, Ethics Division (OGC/ED).

Consensus of the attendees was to offer the course twice per year and to add a second level course (e.g., “Ethics 102") to provide further education on details of functioning in and managing an ethics office. In addition, ideas may be sought from the new HHS OGC/ED

ACTION: The NIH ethics community will send content ideas for the two levels to Traci Melvin within the next few weeks. Ms. Melvin will work on draft curricula for the two courses.

3. HHS Annual Deputy Ethics Counselors’ Workshop for 2004 Gretchen Weaver

The 2004 HHS DEC Workshop is scheduled for Tuesday, December 7, 2004, at Lister Hill Auditorium on the NIH campus (Bldg 38A). Registration materials will be distributed very soon.

4. Update on Regulations Holli Beckerman Jaffe

The supplemental regulation, which is still in DRAFT form, is a change to the HHS departmental supplemental standards of ethical conduct regulation which supplements OGE's government-wide standards of conduct regulation. Hence, both HHS and OGE need to approve the regulation before

it is final, and the proposed regulation is still UNDER REVIEW. That means it is still SUBJECT TO CHANGE. While it is unlikely that the three major provisions will change -- outside activities, prohibited holdings, and awards -- the specifics of these provisions may. To avoid misunderstandings with employees later, please continue to discuss the coming changes with employees in general terms only.

Proposed changes include:

- Outside Activities:
  1) A prohibition on all employees from engaging in consulting or employment with a pharmaceutical or biotechnology company. The definition of pharmaceutical and biotechnology companies may be based on the definition used at the US Food and Drug Administration (FDA), and will exclude food companies. Companies will be identified using the same mechanism as used at FDA, e.g., the "yellow book".
  2) A prohibition on all employees from receiving compensation for any paid activities with grantees, other than the already permitted exception for teaching provided in the Standards of Ethical Conduct (5 CFR 2635.807(a)(3)).

- Prohibited Holdings: The plan is to have an electronic list of prohibited sources, similar to the FDA procedure.
  1) Both 278 and 450 filers would be prohibited from holding stock in pharmaceutical and biotechnology companies.
  2) It is proposed that 450 filers, either as a class or as an individual, may request and receive an exemption to permit such holdings.
  3) It is possible that non-filers may be permitted to hold up stock valued up to the regulatory *de minimis* level, or possibly no limit.

  Certificate of Divestiture (CD): The new regulation will probably permit 90 days to divest, but employees may request a certificate of divestiture and thus be permitted additional time, pending receipt of the CD. Depending on how many employees request the CD, it may lengthen the time for divesting to permit adequate review and notification of decisions, or for discovery of ways to streamline the CD approval process. Packages must be complete in order to receive a quick response from the Office of Government Ethics (OGE), which must approve the CD. Remind employees that they must wait for the CD before they sell; CDs cannot be retroactive.

  How to Deal with Refusal to Divest (employee or spouse): There is an exception provision in the 450 regulation which may be used very infrequently when an employee has a justifiable reason for not divesting. This is a very rigorous process and is not routinely granted, though may be granted in instances such as the employee is leaving NIH employment within the next several months.

  ACTION: OGC/ED staff will put together samples and instructions to help IC ethics staff produce the required documentation for CD requests. Depending on the number of requests, training may be provided to assist ethics staff to prepare the request packages.

  ACTION: The NIH Ethics Office will plan training for ethics staff in preparation of requests for a Certificate of Divestiture.

- Awards: NIH will institute a new 2-step process for reviewing awards from outside organizations:
  1) First level review will be done by a Working Group of the NIH Advisory Committee to the Director. They will review the award criteria and determine whether the award meets the regulatory definition of bona fide award. The approved awards will be listed on the NIH Ethics Program web site. (See testimony of Marilyn Glynn, Acting Director of OGE; **DAEOgram 04-011**).

2) Each award request will be reviewed on a case-by-case basis to determine whether the individual recipient may accept the associated cash. The award must be on the list of approved awards to accept the honor, but depending on circumstances may not be able to accept the cash portion of the award. NIH policy will define this aspect more than the regulation.

   Exception: Some awards are so prestigious that even if the employee has an official matter pending, the employee could still receive the award, e.g., the Nobel Prize is managed by the Karolinska Institute, which receives conference grants from the NIH. The employee would still be permitted to receive this prestigious award.

5. Determining Who Files the OGE 450 Holli Beckerman Jaffee

As part of the discussion about the regulation, it was announced that the NIH will implement significant guidance for consistency across the NIH for which employees and positions will be required to file the OGE 450, Confidential Financial Disclosure Report. In addition, guidance about which employees or classes of employees would be exempt. The decision at the NIH level will reduce the discretionary decisions for inclusion or exclusion currently made by the IC Deputy Ethics Counselor.

6. Issues for New Hires into Positions Required to File the SF 278 Holli Beckerman Jaffee

The memorandum from Scott Whitaker re: Ethics Requirements for New 278 Hires (dated Oct. 1, 2004) was forwarded to the NIH DECs and ECs by Traci Melvin on October 12. The memorandum establishes new requirements for ethics orientation, submission of a draft SF278, and implementation of an ethics agreement prior employees entering 278 filing positions. Steps necessary to implement the memo have been drafted by OGC/ED. NIH is continuing to develop NIH policy and requirements to address details not covered by the OGC/ED steps. In the interim, IC ethics staff are asked to follow the steps provided by OGC/ED, and to work with Human Resources and, where appropriate NEO staff, when a candidate is identified for a position which requires filing the Public Financial Disclosure Report (SF 278). IC staff will review the SF278 and forward a copy and the plans agreed to be the appointee (e.g. the ethics agreement) for resolution of conflicts to OGC/ED. The ethics agreement may be as formal as an agreement document, or may be less formal, such as an email exchange. Actions to avoid conflict will be identified during the ethics orientation and review of the financial disclosure report, and the candidate must agree to the conditions (e.g., resign from outside job) prior to entering on duty at the NIH.

Ethics staff need to work with Human Resources staff to ensure that all vacancy announcements include notice of the need to file a financial disclosure report.

If the final candidate is a current NIH employee, and already files a public financial disclosure report, there is no need for a draft new entrant report. The last report filed will be reviewed by IC ethics staff (and NEO staff, where appropriate) again for potential conflict in the new position, and the remainder of the new requirements followed, e.g., ethics agreement, orientation with OGC/ED staff. The 'orientation' may cover specific topics or may be more broad, depending on the contents of the SF278 and the type of information which OGC/ED staff feel the employee needs to hear.

ACTION: Ms. Weaver will provide the **preliminary procedure** for distribution with the minutes.

ACTION: Ms. Jaffe will send out the memo and information to the DECs and ECs again.

ACTION: The NIH Ethics Office will plan training for ethics staff in preparation of ethics agreements.

7. Working Groups Updates — Anne Stroh

Training: The NIH Ethics Office will try to set up additional NIH-wide sessions for annual ethics training for 2004. If an employee refuses to attend, there are administrative actions that may be imposed, using the Table of Penalties in the Human Resources policy. For example, the IC DEC may verbally counsel the employee that training is a condition of employment, or may give a verbal or written reprimand, depending on the level of refusal, past history, etc.

ACTION: ICs will train their own "Top 5" employees and send the certificates to the NIH Ethics Office.

Official Duty Activities / Outside Activities: The group is incorporating the criteria for when a written or verbal official duty request is required, and incorporating it into a draft NIH policy chapter. They expect to distribute it to the ethics community for review within the next several weeks. Discussion by the attendees included explaining the need for a thorough conflicts review versus avoiding micro-management of the IC programs by the NIH Deputy Ethics Counselor, yet maintain consistency across the NIH. The Working Group is working on appropriate language.

A checklist for the Outside Activity request package is being drafted.

Financial Disclosure: The Working Group will re-convene to help draft the NIH-wide criteria for which employees will be required to file the Confidential Financial Disclosure Report (OGE 450), or excluded from filing.

Database: Multiple activities are moving ahead concurrently:

- Revisions to the NIH Ethics Management Information System (EMIS) have been submitted to the Office of Information Technology (OIT) in the OD. The resulting system will be EMIS version 2.0, expected to be ready for use in early 2005. (Current version is termed EMIS version 1.0.). ICs with data to import into EMIS area encouraged to contact OIT to initiate the process.
- A **Data Dictionary for EMIS 1.0** is available on the EMIS web site. A link is available from the NIH Ethics Program web site What's New page and from the EMIS main page (not inside the EMIS system).
- The NIH Center for Information Technology (CIT) is continuing to gather information on the needs and scope of an enhanced ethics system, to be developed over the next two years. This system will have significantly more functions and conflict of interest analysis capabilities.

8. Announcements — Traci Melvin

- Contractors and COI: Several ICs have requested information on dealing with contract employees, e.g., are they required to attend the ethics training. It was announced at the recent IC Directors' meeting that contractors have some conflict of interest requirements. NIH has authority to include specific terms in contracts to require adherence to conflict of interest issues, e.g., IRTAs are subject to COI regulations as part of their agreement.

- OGE Prosecution Survey: In 2003, two federal employees were prosecuted for accepting gift cards from a vendor, considered a violation of 18 USC 209 (illegal supplementation of salary). The OGE **Prosecution Survey** is an excellent source of examples to use in your training, and a resource for understanding how certain activities can be analyzed under the laws.

- Letters to the INS (representation issues): Several questions have arisen regarding whether it is considered representational activities to write letters to the Immigration and Naturalization Service on behalf of other individuals. There is HHS guidance from several years ago which is currently

being revised, and will be distributed across the Department as soon as it is ready. For now, employees should refrain from writing letters to INS on behalf of other individuals unless specifically requested to do so through official channels (e.g., the official request from the State Department on visa issues).

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